510(k) SUMMARY
807.92(c)

K112735

NOV - 2 2012

SPONSOR

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Summary Preparation Date: October 08, 2012

DEVICE NAME

Trade Name:	Tamarin Blue® PTCA RX Dilatation Catheter
Common/Usual Name:	PTCA RX Catheter
Classification Name:	Catheters, transluminal coronary angioplasty, percutaneous
Regulation Number:	870.5100
Product Code:	LOX
Device Class:	Class II

PREDICATE DEVICE

Legally Marketed Equivalent Devices:

- Maverick 2 PTCA Catheter - Boston Scientific Corporation – P860019
- Sprinter Legend Rapid Exchange Balloon Dilatation Catheter – Medtronic Ireland – P790017
- Trek ™ RX Coronary Dilatation Catheter - Abbott Vascular Inc. – K103110

DEVICE DESCRIPTION

The Tamarin Blue® PTCA RX Dilatation Catheter is a standard Rapid Exchange (RX) PTCA catheter with a single lumen proximally, a dual lumen distally, a semi-compliant inflatable balloon and a soft, tapered distal tip to aid in crossing tight stenoses. One lumen of the catheter's dual lumen is used for inflation and deflation of the balloon, and the other lumen allows guide wire access through the distal part of the catheter. The maximum recommended guide wire diameter is 0.014". A luer lock fitting (Hub) allows

connection with an inflation device. Two radiopaque markers on the guide wire lumen tubing provide visual reference points for balloon positioning across the stenosis. The balloon material expands to a known diameter at specific pressure as defined in the compliance table supplied with the catheter. The device is available in the balloon diameters and lengths shown in the table below:

		Diameter (mm)								
		1.50	2.00	2.25	2.60	2.75	3.00	3.25	3.50	4.00
Length (mm)	8	✓	✓	✓	✓	✓	✓	✓	✓	✓
	12	✓	✓	✓	✓	✓	✓	✓	✓	✓
	15	✓	✓	✓	✓	✓	✓	✓	✓	✓
	20	✓	✓	✓	✓	✓	✓	✓	✓	✓
	25		✓	✓	✓	✓	✓	✓	✓	✓
	30		✓	✓	✓	✓	✓	✓	✓	✓

It will be supplied sterile and is intended for one time use.

DEVICE INTENDED USE

The Tamarin Blue® PTCA RX Dilatation Catheters are indicated for Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion.

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

The Tamarin Blue® PTCA RX Dilatation Catheter uses similar technology, materials and methods of operation as the approved predicates: Maverick2 PTCA Catheter (P860019), Sprinter Legend RX (P790017/S096 & K103095) and Trek ™ RX device (K103110). The properties of the Tamarin Blue® PTCA RX Catheter to treat disease are identical to predicate PTCA balloon dilatation catheters.

Additionally, the Tamarin Blue® PTCA RX Dilatation Catheter incorporates substantially equivalent indications for use, design and dimensional and performance specifications as those found with the aforementioned predicate devices.

NONCLINICAL TESTS

SAFETY and EFFECTIVENESS

BIOCOMPATIBILITY

All materials used in the Tamarin Blue® PTCA RX Dilatation Catheter are biocompatible based on biocompatibility testing results. The device has been tested according to ISO 10993 Part 1, 2, 4, 5, 10, 11, 12, ASTM F756-00 and 21 CFR 58 (GLP regulations).

PERFORMANCE DATA

The safety and effectiveness of the Tamarin Blue® PTCA RX Dilatation Catheter has been evaluated in the following non-clinical tests:

- Biocompatibility
- Balloon compliance
- Balloon burst pressure
- Balloon fatigue (repeated balloon inflation) endurance
- Balloon inflation/deflation performance
- Bond strengths
- Catheter dimensions and balloon profile
- Catheter body minimum burst strength
- Device preparation (guide wire and introducer compatibility)
- Flexibility and Kink
- Torque
- Radiopacity
- Coating integrity
- Particulate evaluation

CONCLUSION

The Tamarin Blue® PTCA RX Dilatation Catheter met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, and test protocols.

The Tamarin Blue® PTCA RX Dilatation Catheter has the same intended use, similar design and technological characteristics, equivalent performance properties, identical sterilization and packaging, same mode of operation, and no new safety or effectiveness issues. Therefore, the Tamarin Blue® PTCA RX Dilatation Catheter is considered substantially equivalent to the aforementioned predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

NOV 20 2012

Natec Medical Ltd
c/o Judy Danielson
Senior Regulatory Consultant
CardioMed Device Consultants, LLC
5523 Research Park Drive, Suite 360
Baltimore, MD 21228

Re: K112735
Trade/Device Name: Tamarin Blue® PTCA RX Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Catheters, transluminal coronary angioplasty, percutaneous
Regulatory Class: Class II
Product Code: LOX
Dated (Date on orig SE letter): October 11, 2012
Received (Date on orig SE letter): October 15, 2012

Dear Ms. Danielson:

This letter corrects our substantially equivalent letter of November 2, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number:	K112735
Device Name:	Tamarin Blue® RX PTCA Dilatation Catheter
Indications for Use:	The Tamarin Blue® RX PTCA Dilatation Catheters are indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K112735